

Public Health Comments
Regarding Fast Track /Trade Promotion Authority
Hearing of the House Committee on Ways and Means
“Expanding American Trade with Accountability and Transparency”
April 22, 2015

Concerning the:

Bipartisan Congressional Trade Priorities and Accountability Act of 2015

Working Title:

"Bargaining to Concentrate the Power and Wealth of Global Corporations Including Finance, Drugs, Tobacco, Fossil Fuel, Agribusiness, Media and Information Technology; to Entrench and Deepen Income Inequality; and to Progressively Reduce the Rights and Policy Space of People and Democratically Elected Public Officials and Governments"

Joseph E. Brenner MA and Ellen R. Shaffer PhD MPH
Co-Directors
Center for Policy Analysis on Trade and Health (CPATH)

CPATH • P.O. Box 29586, San Francisco, CA 94129-0586
phone: 415-922-6204 • ershaffer@cpath.org • www.cpath.org

Overview

On behalf of the Center for Policy Analysis on Trade and Health (CPATH), we appreciate the opportunity to comment on the proposed Congressional Trade Priorities and Accountability Act of 2015. CPATH is an independent organization that has been involved for many years in bringing a public health voice to debates on trade and sustainable development through research, policy analysis, and advocacy.

A raft of complex trade agreements with sweeping implications for the public's health are being negotiated by the U.S. Trade Representative (USTR) in secrecy, shielded from the light of public scrutiny. These include the Trans-Pacific Partnership Agreement (TPP) with 11 Pacific Rim nations, the Transatlantic Trade and Investment Partnership (TTIP) with the European Union, and the Trade in Services Agreement (TISA). Unfortunately the USTR has relied on Trade Advisors representing the [pharmaceutical](#), [tobacco](#), [alcohol](#), [health insurance](#), and [processed food](#) industries in shaping the Administration's trade objectives and negotiating positions relating to public health and health care.

These deals confer new and expanded rights to transnational corporations to protect their profits over the rights of democratically elected governments and the public. These include the right to challenge the implementation of domestic laws and regulations in international trade tribunals.

This bill would create a Fast-Track process to allow trade agreements to leapfrog customary legislative protocol, and be put to a rapid "up or down" vote in Congress without public hearings or amendments, including those in the interest of protecting the health and safety of the American people.

The Fast Track bill also aims to set out Congress' policy objectives for trade agreements, as well as an undemocratic and abbreviated process for reviewing them. As an illustration of this fatally flawed legislation, not one objective would safeguard or improve the economic well-being of the American middle class. Rather, they prioritize commercial gain at the expense of people's health, including access to affordable medicine, protection from deadly tobacco products, and democratic sovereignty to make decisions to safeguard and improve our health.

A more appropriate title would be: Bargaining to Concentrate the Power and Wealth of Global Corporations Including Finance, Drugs, Tobacco, Fossil Fuel, Agribusiness, Media and Information Technology; to Entrench and Deepen Income Inequality; and to Progressively Reduce the Rights and Policy Space of People and Democratically Elected Public Officials and Governments.

Promote Democratic, Transparent, and Accountable Trade Negotiations

In order to create trade agreements that advance the promises of the 21st century for sustainable technological and economic development that protect and promote health, CPATH recommends that Congress adopt and enforce robust objectives for the TPP Trade Agreement negotiations that will safeguard the health of Americans and our trading partners, and promote economically and socially just, democratically controlled, and environmentally sustainable outcomes, specifically the following Public Health Objectives for Global Trade Agreements:

Public Health Objectives for U.S. Global Trade Agreements

1. **Assure democratic participation by public health and transparency in trade policy:**
 - a. Open all proceedings and documents of trade negotiations and trade advisory committees to the public; and
 - b. Appoint to all three tiers of trade advisory committees representatives of organizations that work to assure equitable access to affordable health-related services and products, and promote the health of individuals, communities and populations, who can provide formal advice to USTR from the public health and health care community to USTR; and
 - c. USTR to consult with all relevant committees of the House and Senate in the development, negotiation, implementation, and administration of trade and negotiating objectives.
2. **Develop mutually beneficial trade relationships with trade partners that create sustainable economic development** in an increasingly interdependent world.
3. **Recognize the legitimate exercise of national, regional and local government sovereignty to protect population health**, and ensure that countries do not weaken or reduce, as an encouragement for trade, sound policies that contribute to health and well-being and democracy, including laws on public health, the environment, labor, food safety, human rights and internet freedom.
4. **Exclude tariff and nontariff provisions that address vital human services** such as health care, water supply and sanitation, food safety and supply, and education, including licensing and cross-border movement of personnel in these fields.
5. **Exclude tobacco and tobacco products**, which are lethal, and for which the public health goal is to reduce consumption, from tariff and nontariff provisions of the TPP, including advertising, labeling, product regulation and distribution.
6. **Exclude alcohol products**, which present serious hazards to public health. Policies designed to reduce the harm caused by alcohol products should not be subject to compromise in exchange for other trade benefits.
7. **Eliminate intellectual property provisions related to pharmaceuticals from the TPP and TTIP negotiations**, as these are more appropriately addressed in multilateral fora, **and promote trade provisions which enable countries to exercise all flexibilities provided by the Doha Declaration on Public Health**, including issuing compulsory licenses for patented pharmaceuticals, parallel importation, and other measures that address high prices and promote access to affordable medicines.

The outline of the following comments is as follows:

1. Economic globalization and health – Overview
2. The track record: trade and health
3. Transparency and democracy
4. Intellectual property rules limit access to affordable medicines
5. Tobacco corporation challenges to tobacco controls
6. Investor-state dispute resolution

Conclusion: Oppose the Bipartisan Congressional Trade Priorities and Accountability Act of 2015

1. Economic globalization and health - Overview

Economic globalization is characterized by the accelerated number and pace of cross-border transactions starting in the 1980s, including the production and consumption of goods and services, facilitated by changes in communication, technology, and transportation. Services from finance to health care are major economic drivers in developed countries. Ownership of transnational corporations has become more concentrated. Millions in poor countries have emerged from poverty, at the same time that economic inequality is increasing among and within nations.

At issue are the roles that democratically elected public officials, civil society, unregulated trade as well as rules related to trade, will and should play in determining outcomes of economic activity that benefit population health, and how the imperatives of human social and economic development can be integrated.

Public health principles prioritize achieving and protecting the health and wellbeing of individuals, communities and populations, which in turn requires economic and social equity and justice, democracy, and equitable access to health-related services.

Trade agreements establish countries' mutual rights and obligations with regard to trade. Once focused on setting tariffs on goods, they now address rules that govern critical areas that are a matter of public debate at the national and international levels: intellectual property rules on access to affordable medicines and to information, copyrights, and advertising; services ranging from banking to health care and water supply; government procurement for grants and contracts; agriculture; and internet access and information privacy. They can provide a basis for altering the implementation of domestic U.S. laws and policies, as well as those of our trading partners. Trade rules that protect corporations' ability to operate within uniform and predictable rules can foster sustainable economic development, democracy, and peace, consistent with public health principles that prioritize achieving and protecting the health and wellbeing of individuals, communities and populations.^{1 2} They can also conflict with or subordinate policies that prioritize people's health, and equitable access to health-related services.

2. The Track Record: Trade and Health

Health is a universal aspiration of all peoples and governments. People's health must be the highest priority in determining trade policies. Public health measures have been responsible for creating and monitoring the conditions that maintain a healthy population. The safety of our living spaces, work places, prescription drugs, food and water, and consumer products, and protection from biohazards and the burden of tobacco-related diseases, are all products of government action, legislation and regulation, not the result of unregulated market forces.

Previous trade agreements negotiated under "fast track" rules, without Congressional ability to discuss, debate, and revise provisions in the public interest, have prohibited parallel importation

¹Institute of Medicine. The future of public health in the 21st century. National Academies Press, Washington, DC. November, 2002. <http://www.iom.edu/Object.File/Master/4/165/0.pdf>

²World Health Organization. Constitution of the World Health Organization.

(reimportation of pharmaceuticals to increase their affordability)³, and weakened the ability of local, state and national governments' procurement contracts to specify standards for medical and financial privacy, quality and performance, local economic development, and environmental protection.

Other public health concerns at issue include the ability of local, state and national governments to regulate clean and safe air, water, food, consumer products; workplace environments, transportation systems; whether government procurement contracts can specify standards for medical and financial privacy, quality and performance, local economic development, and environmental protection; and the distribution of alcohol beverages.

3. Transparency and democracy: U.S. trade policy is set in secret by corporate trade “advisors.” Trade agreement negotiations are kept secret from the public in the U.S.

An extensive group of advisory committees provide formal recommendations to the Office of the U.S. Trade Representative (USTR).

Confidentiality of Trade Proposals Prevents Democratic Debate

The USTR can authorize advisory committees to operate in a transparent, public manner. For a number of years, however, the USTR has chosen impose a blanket closure rule, requiring that advisory committee members maintain complete confidentiality regarding proposed trade agreement provisions until after each agreement is signed. This restriction limits debate by Committee members' own constituencies, by the public, and by policy-makers, on public health matters of significant domestic concern. A transparent mechanism is imperative.

Trade Advisory Committees Shut Out Public Health

In 2002, the United States Government Accountability Office (then the General Accounting Office) examined the role, structure, and system of the trade advisory committee system. **The GAO Report found that “new stake holders in the trade process, such as public health...have limited or no participation in the formal committee system,** even though topics such as intellectual property are of interest to them.”⁴

CPATH's analysis has found that health-related industries are robustly represented on US trade advisory committees, which include pharmaceuticals, tobacco, health insurance, processed foods, and alcohol beverages.⁵ A public health presence on all three tiers of U.S. trade advisory committees is required for a legitimate balance of interests. However, the extent of representation from the public health community in 2015 persists: Zero.

In November, 2003, U.S. health leaders called for caution in negotiating international trade agreements. Former U.S. Surgeon General Dr. David Satcher, joining representatives from the

³ Australia-U.S. Free Trade Agreement, Article 17.9.4.

http://www.ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file469_5141.pdf.

⁴ GAO-02-876, p. 60; P.L. No. 96-39, 93 Stat. 308-10, p.40.

⁵ Brenner, Joseph and Shaffer, Ellen. Advice and No Dissent, *Public Health and the Riggged U.S. Trade Advisory System*, Multinational Monitor, November 2004 - VOLUME 25 - NUMBER 11.

American Medical Association, American Nurses Association, the American Public Health Association, and the Center for Policy Analysis on Trade and Health (CPATH), to issue an historic “Call for Public Health Accountability in International Trade Agreements.”

During the 2004 Congressional deliberations on the US-Australia Free Trade Agreement (FTA), Bipartisan members of the House and Senate expressed concerns about the extreme imbalance on trade advisory committees and lack of representation from public health. Congress raised objections to provisions in the agreement related to pharmaceuticals and intellectual property that they had been unaware of that could have an impact on Congressional efforts to authorize re-importation of drugs. They also expressed concern about the potential impact on current U.S. health care programs, including on Veterans Affairs, Medicare and Medicaid, and urged that such provisions should not serve as precedent for future trade agreements.

In March, 2014, USTR announced a call for nominations to a [Public Interest Trade Advisory Committee](#). However, no action has been taken to establish this committee.

4. Intellectual Property Rules limit access to affordable medicines

High prices restrict access to prescription drugs in lower income countries and also in developed countries which lack regulatory mechanisms to address drug pricing, such as the United States. Few useful innovative drugs are being developed, despite substantial revenue from drug sales. There is insufficient research into therapies for conditions prevalent in low-income countries.

Trade agreements negotiated by the United States have enforced, extended, and progressively strengthened intellectual property (IP) rights internationally, such as patents, data exclusivity and linkage, that offer monopoly marketing rights to pharmaceutical companies which therefore exert tremendous influence over prices. The World Trade Organization’s (WTO) Doha Declaration on Public Health states that IP rules “should not prevent [countries] from taking measures to protect public health.” It reaffirms the right of WTO countries to use the flexibilities in TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights), including their right to issue compulsory licenses to produce brand name or generic equivalents of originator companies’ drugs, and parallel importation. Respect for the Doha Declaration, and a fair balance of rights, was also stated as a Congressional objective in the Trade Act of 2002.

These rights were eroded in U.S. bilateral and regional agreements with Jordan, Chile, Singapore, Morocco, Australia and Central America. Civil society organizations in the U.S. and in partner nations raised concerns, which frequently delayed negotiations. In May, 2007, with leadership by the Trade Subcommittee of the Ways and Means Committee, Congress took action to limit negotiations with lower income countries on “TRIPS-Plus” IP rules.

“Fast-track” negotiating objectives in the current proposed legislation however reverse course and call for “accelerated” implementation of drug patent rules in developing nations.

- **CAFTA Raises Prices, Limits Availability of Life Saving Drugs for U.S. Trade Partners**
CPATH’s report published in the peer-reviewed journal *Health Affairs* demonstrated how intellectual property rules in the U.S. - Central America Free Trade Agreement (CAFTA) keeps lower-priced generic versions of life-saving drugs off the shelves and out of the hands of some of the poorest

people in our hemisphere. Guatemala is increasingly unable to produce or import affordable medicines because of intellectual property provisions in the trade deal that were demanded by the U.S. pharmaceutical industry and have been aggressively enforced by the U.S. Trade Representative (USTR). As a result, **the cash-strapped Guatemalan public sector faces higher prices – up to 846 percent higher – for important drugs to fight diseases such as diabetes and HIV/AIDS.**⁶ People with HIV/AIDS have reported cutbacks in access to needed drugs

The report focused on **data exclusivity rules** and **patents** that are among the intellectual property provisions of CAFTA and other free trade agreements. Particularly alarming is that the rules not only keep affordable new generics from entering the market; they also function retroactively to remove existing medicines from the shelves. While patents already allow brand name drug manufacturers like Novartis and Merck to suppress competition from generic drug makers in the U.S. and abroad, data exclusivity is an additional bonus for this multi-billion dollar industry. Securing data exclusivity is a simple process for these companies, but it places insurmountable bureaucratic burdens on generics manufacturers. Generic drug makers typically rely on the clinical trial data already generated by brand-name manufacturers to demonstrate the safety and efficacy of their products. But CAFTA prohibits generic drug manufacturers from using the brand-name clinical trial data for a fixed period of years, sometimes even after the brand-name drug is no longer under patent. Without these data, generic versions cannot be approved for market.

The report examined a total of 77 data-protected drugs. Detailed tables in the article illustrate the ways in which both patent and data exclusivity protections influence Guatemalan health officials to purchase brand name pharmaceuticals, often at hundreds of times the cost of their generic counterparts. They also provide examples of generic drugs that were blocked from being marketed in Guatemala in the first place.

5. Tobacco Control and Protection of Public Health

Tobacco use continues to be the leading preventable cause of death in the United States and worldwide, and is the only legal substance that, when used as intended, kills people, causing 6.3 million deaths a year.⁷ Cigarette smoking is responsible for about one in five deaths annually⁸ and a major contributor to the global pandemic of tobacco-related non-communicable diseases.

Countries continue to tackle this public health crisis with sound policies designed to curb smoking and combat deceptive industry practices. Such regulations include bans on flavored cigarettes, increases in tobacco taxation, restrictions on tobacco advertisements, and placement of graphic warning labels on cigarette packages. Although all of these policies are supported by a robust body of scientific evidence, each has been contested in recent trade agreements and by trade-related

⁶ Shaffer, Ellen R. and Brenner, Joseph E., [A Trade Agreement's Impact On Access To Generic Drugs](#), *Health Affairs*, 28, no. 5 (2009): w957-w968 (published online 25 August 2009; 10.1377/hlthaff.28.5.w957)

⁷ Centers for Disease Control and Prevention. Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004. *Morbidity and Mortality Weekly Report* 2008.

⁸ U.S. Department of Health and Human Services. *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2010.

challenges. Tobacco companies have accelerated their use of trade rules to attempt to delay and reverse tobacco control measures in the U.S., Australia, Uruguay, and Norway.⁹ For example:

“In 2006, the Uruguayan government—led by then-President and oncologist Tabare Vasquez, MD—passed a series of regulations to: (1) increase warning labels from 50% to 80% of the package; (2) place health images on packages; and (3) prohibit the use of “brand families” in which the same brand name is used across multiple product lines (eg, Marlboro Red, Marlboro Green, etc). In the years after enactment of these anti-smoking laws, 30-day prevalence rates of tobacco use among adolescents decreased by 8% annually, and per person cigarette consumption decreased by 4.3% annually. In 2010, however, the Swiss operational hub of Phillip Morris filed suit at the World Bank, claiming that government’s regulations violate a 1991 bilateral investment treaty between Uruguay and Switzerland. The Swiss-based PM contends that Uruguayan policies intrude upon PM’s intellectual property and exceed that which is reasonable to protect the public’s health. Per the terms of the 1991 trade agreement, the dispute is being arbitrated by a tribunal of international trade experts housed at the World Bank, who ruled in July 2013 that it had jurisdiction to hear the case; each side is currently submitting testimony to support their claims.”

U.S. bilateral agreements with Singapore and Peru also eliminated tariffs on tobacco and tobacco products.

The Doggett Amendment to the Foreign Service Act, passed by Congress in 1997, banned the use of government monies from the Commerce, Justice, and State Departments to promote the sale or export of tobacco overseas or to seek the removal of any nondiscriminatory foreign-country restrictions on tobacco marketing. However, it is subject to annual renewal, and compliance is up to the USTR and other Agencies. Unfortunately, the Doggett Amendment has not been honored since 2001. The U.S. has negotiated eliminating tariffs on tobacco products as well as leaf in bilateral and regional agreements, including the U.S. Singapore Agreement and CAFTA. It is perhaps time for a change.

According to the Pan American Health Organization: “Transnational tobacco companies...have been among the strongest proponents of tariff reduction and open markets. Trade openness is linked to tobacco consumption.”¹⁰

The extent to which the TPP will further destabilize existing tobacco control policies is unknown, largely because negotiation of trade rules and tobacco industry activity in the trade arena occur in secret, outside of public scrutiny. Analysis of the Intellectual Property Chapter draft of the TPP that was made public in 2014 found multiple potential threats to tobacco-control measures, and the sovereign ability of nations to protect public health from tobacco-related disease and death.¹¹

⁹ Sud S, Brenner JB, Shaffer ER. [Commentary](#): Trading Away Health: The Influence of Trade Policy on Youth Tobacco Control. *Journal of Pediatrics*. Online: Feb. 10, 2015. DOI: <http://dx.doi.org/10.1016/j.jpeds.2015.01.016>

¹⁰ D. Woodward, N. Drager, R. Beaglehole, D. Lipson. Trade in Health Services: Global, Regional and Country Perspectives.

¹¹ Center for Policy Analysis on Trade and Health. Intellectual Property Chapter of Trans-Pacific Partnership Trade Agreement, Tobacco, and Public Health, November 25, 2013.

http://www.cpath.org/sitebuildercontent/sitebuilderfiles/TPP_IP_TobaccoNov25_2013.pdf

Only through appropriate public and Congressional oversight will we ensure that the TPP does not undermine the right and ability of the U.S. or participating countries from exercising their domestic sovereignty in order to adopt or maintain measures to protect public health, including reducing tobacco use and to prevent the harm it causes to public health.

6. Investor-State Dispute Resolution

WTO agreements are enforced by financial fines and trade sanctions in the case of violations. For this reason, they have proven to be the most effectively enforced international agreements. The WTO is set as the unequivocal arbiter of trade rules for its 160 member countries. Countries that believe their companies are being barred from trade by another country for reasons that violate WTO rules can file a dispute with the WTO. Disputes among nations are resolved by panels appointed by the WTO. The panels are not accountable to national governments or courts. The panels can authorize countries to impose trade sanctions, financial penalties and the boycott of products against other countries, as compensation for violations or for failure to comply with trade panel decisions.

Nations have successfully brought challenges before trade tribunals claiming that public health measures violate trade rules. Health and quality standards and labeling requirements have sometimes been construed by the World Trade Organization as barriers to trade. From a public health perspective, standards for labeling genetically modified foods or protecting dolphins from becoming snared in commercial fishing nets are important protections for human and animal health, and the environment. But businesses have found these standards cumbersome, and therefore barriers to trade.

Chapter 11 of NAFTA provides an “investor’s rights” provision that allows individual foreign corporations (referred to as investors) to directly sue any of the three participating national governments. Companies can sue for the loss of current or future profits, even if the loss is caused by a government agency’s prohibiting the use of a toxic substance. Prior to NAFTA, regional trade agreements only permitted country-to-country enforcement by governments. This was a major elevation of the rights of corporations, and an important blow to national sovereignty. Subsequent regional and bilateral agreements negotiated by the US include the investor’s rights provision. Objections by the Intergovernmental Policy Advisory Committee to the USTR, composed of state and local public officials, contributed to keeping this provision out of the U.S.-Australia Free Trade Agreement.

The tobacco industry has used both WTO country-to-country dispute procedures, and investor-state mechanisms, to protest and delay tobacco control measures including graphic warning labels and plain packaging, as described above.

The following investor-state trade dispute cases illustrate the negative implications for health. As is typical of such cases, the health argument did not substantially prevail. The Methanex case, an exception, nevertheless extended exposure to a known health hazard:

- **Closure of a Toxic Waste Disposal Site**

In a landmark environmental case filed under NAFTA Chapter 11, a NAFTA tribunal awarded the U.S.-based Metalclad Company \$16.7 million in its suit against Mexico. The state of San Luis Potosí had refused permission for Metalclad to re-open a waste disposal facility, in the face of a geological audit showing the facility would contaminate the local water supply and resulting opposition by the

local community. Metalclad claimed that this local decision constituted an expropriation of its future potential profits and successfully sued Mexico.

- **Eliminating Toxic Gasoline Additive**

The Methanex Corporation of Canada sued the United States for approximately \$1 billion, because the state of California banned the use of methyl tertiary butyl ether (MTBE), a gasoline additive. Though introduced to reduce air pollution, MTBE was found to be carcinogenic when it leaked into the water supply. Methanex produces methanol, a component of MTBE. Methanex ultimately lost its case, because the trade panel cast doubt on whether the state intended to discriminate against Methanex as a foreign corporation. However, due in part to the possible sanctions resulting from this case, MTBE remained in use within California for years as the case proceeded, The U.S. Dept. of Justice spent millions defending the case.

These cases suggest two policy remedies for public health:

1. Eliminate the investor-state mechanism that permits foreign corporations to file trade charges against sovereign governments.
2. Trade agreements should exclude health-related laws and regulations from trade challenges at both the country-to-country level, through the WTO, and from challenges by corporations through bilateral and regional agreements.

Conclusions

CPATH recommends that Congress:

- Incorporate the Public Health Objectives for U.S. Global Trade Agreements as U.S. negotiating objectives.
- Conduct hearings, solicit public comment, and take other appropriate investigatory and oversight actions in all relevant Committees in Congress to assess the impact of past, pending and current trade agreements on population health, and assure based on such assessment that these agreements do not have an adverse impact on health.
- Mandate the appointment to all relevant trade advisory committees representatives of organizations that work to assure equitable access to affordable health-related services and products, and promote the health of individuals, communities and populations.
- Promote transparency and democratic accountability at all levels of the trade negotiation process, including enabling public access to all trade advisory committee meetings, proceedings and submissions related to multilateral and bilateral trade negotiations.
- Exercise its power and authority concerning trade agreements negotiated by the U.S.; retain its rightful authority for review, discussion and revision of the TPP and all future trade agreements in the interest of protecting the health and safety of the American people; and oppose the Bipartisan Congressional Trade Priorities and Accountability Act of 2015.